

REMARKS

Currently Claims 7, 8 and 9 are pending. Claim 5 is cancelled herein. Claims 1-4 and 6 were previously cancelled. Claim 8 is amended to remove "solvate." Claim 7 is amended to change "dichloride" to "dihydrochloride," overcoming the objection of this claim. These amendments do not introduce new matter. Entry of the foregoing amendments is respectfully requested.

Section 112 Rejection Overcome

The rejection of claims 5, 7 and 8 under section 112, first paragraph as non-enabling for "solvates" of the compound is overcome by the foregoing amendment.

Section 102(a) Rejection Overcome

Claims 5, 7 and 8 currently stand rejected under 35 U.S.C. §102(a), the Office Action stating that the claims are anticipated by "Melotto." Applicants understand "Melotto" to be referring to PCT Publication No. 2004/091617. If the Examiner intended a different reference by "Melotto," the rejection is so unclear as to preclude response. Applicants respectfully traverse this rejection.

Melotto '617 was filed internationally on 16 April 2004, published on 28 October 2004, and is assigned to GGL. The instant application claims priority to GB Application No. 0403149.8, filed 12 February 2004. The instantly pending claims are supported by the disclosure and claims of the GB priority application, see, e.g., priority application claims 1-8 and page 2, lines 15-16. Thus, the instantly pending claims are fully entitled to the benefit of the priority date, 12 February 2004. The priority date is before the publication date of Melotto '617, 28 October 2004. Thus, Melotto '617 is not prior art under §102(a) to the instant application. Withdrawal of this rejection is respectfully requested.

Section 102(e) Rejection Overcome

Claims 5, 7 and 8 currently stand rejected under 35 U.S.C. §102(e), as anticipated by "Melotto." Applicants respectfully traverse this rejection.

As pointed out above, the cited reference did not publish before the priority filing date of the instant application. The 102(e) date of the cited reference is the date of filing the

international application, *i.e.*, 16 April 2004. Thus, the priority date of the instant application is before the filing date of the cited reference and accordingly, the cited reference does not qualify as prior art under §102(e). Withdrawal of this rejection is respectfully requested.

Double Patenting Rejection Overcome

Claims 5, 7 and 8 are provisionally rejected on the ground of non-statutory obviousness-type double patenting, the Office Action stating that the claims are not separately patentable over claims 19 and 20 of co-pending Application No. 10/552,870. Applicants respectfully traverse this rejection.

It is the Office's practice to issue a restriction between claims to methods of treatment utilizing a claimed compound and claims to methods of treatment utilizing a combination of the compound with another active agent. The Office has on many instances taken the position that such claims are drawn to patentably distinct inventions and have required and garnered substantial additional fees for divisional applications necessitated by such restriction. In the instant case, the Examiner provides no rationale to support the conclusion that the claimed inventions would be obvious one over the other. That both are drawn to methods of treatment does not support the Examiner's conclusion that the instantly claimed methods of treatment would render obvious, treatment with a combination. It is respectfully submitted that the rejection fails to make out a *prima facie* case of obviousness and is therefore improper and should be withdrawn. Withdrawal of this rejection is respectfully requested.

Applicants respectfully submit that the instant application is in condition for allowance, which action is respectfully requested. The Examiner is invited to contact the undersigned at (919) 483-8222 to discuss this case, if desired.

Respectfully submitted,



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